ISRCTN80908109 https://doi.org/10.1186/ISRCTN80908109

Effectiveness and safety of tenofovir disoproxil fumarate in chronic hepatitis B patients

Submission date
04/04/2023

Recruitment status
No longer recruiting

Registration date
19/06/2023

Overall study status
Completed

Last Edited
13/06/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
HBV infection is particularly important in the Asian-Pacific region and China. Tenofovir disoproxil fumarate (TDF) was approved for the treatment of Chronic Hepatitis B (CHB) in the U.S. in 2008 and in China in 2013 based on Phase III clinical trials results. Since launching in China in 2014, the treatment experience of TDF is limited due to poor access. One important reason was the lack of real-world evidence on long-term effectiveness and safety of TDF among Chinese CHB patients to guide clinical practice. The generation of real-world evidence from this study will provide clinical guidance to Chinese healthcare care professional, address their concerns, and aid public health decision making on resource allocation. To assess the effectiveness among overall and sub-group Chinese CHB patients who receive TDF treatment in real-world.

Who can participate?
TDF-naïve patients with confirmed diagnosis of CHB who newly initiate (Viread) monotherapy or combination therapy for the treatment of CHB will be invited to participate in this study

What does the study involve?
The study is a non-interventional real-world study, and participants will be diagnosed, treated, and monitored as in real clinical practice according to their physicians' judgement without additional interventions and procedures. Paticipants data will be collected from lab test reports or medical records via electronic approaches (Smartphone App) at the entry of the study and thereafter at 6-month intervals for 3 years. There are no mandatory visits during the study period, however, according to the CHB clinical practice and CHB management guideline, CHB patients on anti-viral treatment should be monitored for at least every 6 months.

What are the possible benefits and risks of participating?
Not applicable for this non-interventional real-world study.

Where is the study run from?
The Second Affiliated Hospital of Chongqing Medical University (China)

When is the study starting and how long is it expected to run for?
October 2018 to December 2023

Who is funding the study?
GlaxoSmithKline (China) Investment Co., Ltd

Who is the main contact?
Dr Hong Ren, renhong0531@126.com

Contact information

Type(s)
Principal Investigator

Contact name
Dr Hong Ren

ORCID ID
http://orcid.org/0009-0002-0622-6062

Contact details
288 Tianwen Avenue
Nan'an District
Chongqing
China
400060
+86 13983888786
renhong0531@126.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effectiveness and Safety of Tenofovir Disoproxil Fumarate in Chronic Hepatitis B Patients: A 3-Year, Prospective, Real-World Study in China

Study objectives
To assess the effectiveness among overall and sub-group Chinese chronic hepatitis B (CHB) patients who receive tenofovir disoproxil fumarate (TDF) treatment in the real-world.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/09/2018, Ethics Committee of the Second Affiliated Hospital of Chongqing Medical University (288 Tianwen Avenue, Nan'an District, Chongqing, -, China; +86-023-62888436; 1270161476@qq.com), ref: 2019-7-3

Study design
Multi-center prospective longitudinal observational

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Safety, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Effectiveness and safety of tenofovir disoproxil fumarate in chronic hepatitis B patients

Interventions
This was a non-interventional real-world study. Chronic Hepatits B (CHB) patients treated with TDF were included, patient data will be collected at the entry of this study and thereafter at 6-month intervals for 3 years. Enrollment started on 16th July 2019 and ended on 30th November 2020.

Intervention Type
Drug

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tenofovir disoproxil fumarate

Primary outcome measure

Measured using patient records:
1. Complete virologic response (CVR) at weeks of 48, 96, and 144.
2. HBeAg loss and/or HBeAg. seroconversion in HBeAg positive patients at weeks of 48, 96 and 144.
3. HBsAg loss and/or HBsAg seroconversion at weeks of 48, 96 and 144.
4. Transaminase normalization at weeks of 48, 96 and 144.
5. Time to CVR, defined as time from baseline to the first occurrence of CVR (if applicable)

Secondary outcome measures
Measured using patient records:
1. eGFR at baseline, weeks 48, 96, and 144.
2. Confirmed serum phosphate Grade 3 or 4 abnormality (<2.0 mg/dL) at weeks of 48, 98 and 144.
3. Serum phosphate at baseline, weeks 48, 98 and 144.
4. Phosphorus values at baseline, weeks 48, 98 and 144.

Overall study start date
12/10/2018

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Male or female participants aged 12 years and above, at the time of signing the informed consent.
2. Participants who are diagnosed with CHB and meet the criterion of antiviral treatment for HBV infection judged by certified physicians.
3. Participants who newly initiate TDF ((only including brand TDF, Viread, and generic TDF, Beixin and Naxinde, which passed China generic quality consistency evaluation by Apr. 1 2018) monotherapy or combination therapy for the treatment of CHB by the judge of investigators at the study entry.
4. Participants who have already started TDF at the entry of study and will continue to be treated TDF (including brand TDF, Viread, and generic TDF, Beixin and Naxinde, which passed China generic quality consistency evaluation by Apr. 01 2018) with essential medical information record and lab test reports available at the initiation of TDF treatment and follow-up visit.
5. Participants who are able to perform normal activities and seek regular medical care, e.g., willing to regularly perform lab test to monitor the treatment response.
6. Participants or their legal guardians who are capable of providing signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
2,000

Total final enrolment
2000

Key exclusion criteria
1. Participants who have HIV/HCV co-infection.
2. Participants who initiate or continue antiviral treatment of generic TDF which did not pass China generic quality consistency evaluation by Apr. 01, 2018
3. Participants who initiate antiviral treatment of unauthorized TDF in China.
4. Participants with a prior history of receiving any TDF monotherapy or combination therapy without essential lab test report (e.g. HBV DNA level, eGFR, serum phosphate) and medical records available at the initiation of TDF treatment and thereafter follow-up.
5. Participants who participate in any concurrent clinical trials or within 3 months priorto the entry into this study.
6. Participants who are NOT able to upload their information electronically using the study-designed smartphone APP.
7. Inability to comply with study requirements as determined by the study Investigator.

Date of first enrolment
16/07/2019

Date of final enrolment
30/11/2020

Locations

Countries of recruitment
China

Study participating centre
The Second Affiliated Hospital of Chongqing Medical University
288 Tianwen Avenue, Nan'an District
Chongqing
China
400060

Study participating centre
The Fourth Affiliated Hospital of Xinjiang Medical University
No.116, Huanghe road
Shayibake district
Urumqi
Xinjiang
China
830000

Study participating centre
The Third People's Hospital of Taiyuan
No.65, Shuangta west street
Taiyuan
China
030000

Study participating centre
The Fourth Affiliated Hospital of Harbin Medical University
No.37 Yiyuan street
Nangang district
Harbin
China
150000

Study participating centre
Shenyang Sixth People's Hospital
No.85 Heping south street
Heping district
Shenyang
China
110000

Study participating centre
Tianjin Second People's hospital
No.75, Sudi south road
Nankai district
Tianjin
China
300000

Study participating centre
The Third People's Hospital Of KunMing
No.319, Wujing road
Guandu district
Kunming
China
650000

Study participating centre
Qiqihar Seventh Hospital
No.88 Xinming street
Qiqihar city
Qiqihar
China
161000

Study participating centre
The Second Affiliated Hospital of the Air Force Military Medical University
No.1, Xinsi road
Baqiao district
Xi'an
China
710000

Study participating centre
Beijing You'an Hospital Affiliated to Capital Medical University
No.8, xitoutiao, you 'an men wai
Fengtai district
Beijing
China
100000

Study participating centre
Nanchang Ninth Hospital
167 Hongdu middle avenue
Nanchang
China
330000

Study participating centre
Affiliated Hospital of Yunnan University
176 Qingnian road
Kunming
China
650000

Study participating centre

Jilin Provincial Hepatobiliary Hospital
No. 2218, Jingyang road
Changchun
China
130000

Study participating centre
Nanjing Gulou Hospital
321 Zhongshan road
Nanjing
China
230000

Study participating centre
Shenzhen Third People's Hospital
No. 29, Bulan road
Longgang district
Shenzhen
China
518000

Study participating centre
Tongji Hospital affiliated to Tongji Medical College, Huazhong University of Science and Technology
1095 Jiefang avenue
Wuhan
China
430000

Sponsor information

Organisation
GlaxoSmithKline (China) Investment Co., Ltd.

Sponsor details
Building A Ocean International
Center 56, Mid 4th East Ring Rd,
Chao Yang district, Beijing
Beijing
China
100025

+86 10 5925 2888
jiafei.x.yin@gsk.com

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline (China) Investment Co., Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		09/11/2018	13/06/2023	No	No